PAIGE M. TOMASELLI (State Bar No. 237737)
Grime Law, LLP
5630 Venice Blvd. Suite 544
Los Angeles, CA 90019
T: (619) 339-3180
ptomaselli@grimelaw.com

LARISSA LIEBMANN (*pro hac vice*)
CRISTINA KLADIS (State Bar No. 332812)
Animal Legal Defense Fund
525 E. Cotati Avenue
Cotati, CA 94931
T: (707) 795-2533
lliebmann@aldf.org
ckladis@aldf.org

Counsel for Plaintiffs

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ANIMAL LEGAL DEFENSE FUND, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

Case No. 3:20-cv-03703-RS

PLAINTIFFS' REPLY IN SUPPORT OF MOTION TO STRIKE DEFENDANTS' EXTRA-RECORD DECLARATIONS

Date: March 9, 2023
Time 1:30 p.m.
Dept: San Francisco, Courtroom 3
Judge: Honorable Richard Seeborg

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INTRODUCTION

Plaintiffs' Motion to Strike presents a single issue for the Court: whether each of FDA's extra-record declarations fall under the *Lands Council* exceptions to the record review rule. They do not. And while Defendant and Defendant-Intervenor (collectively, "Defendants") argue that the Court should consider both agency declarations if the Court considers Plaintiffs' declaration from Dr. John Tegzes, that is not the law in the Ninth Circuit. FDA's declarations are improper rebuttal declarations that proffer legal conclusions and post hoc rationalizations under the guise of helping the Court review the administrative record. Because FDA has made no showing that its extra-record evidence fits within the Ninth Circuit's limited exceptions to the record review rule, the Court should strike FDA's declarations.

ARGUMENT

Dr. Amey Adams' and Dr. Kimon Kanelakis' declarations are improper extra-record evidence not admissible under the *Lands Council* exceptions. FDA has an evidentiary burden to establish that the Adams Declaration and the Kanelakis Declaration are each *independently* admissible. *San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 993 (9th Cir. 2014) ("[T]he party seeking to admit extra-record evidence initially bears the burden of demonstrating that a relevant exception applies." (citation omitted)). FDA has not carried that burden. Instead, FDA admits that its declarations are explicitly offered to rebut the Tegzes Declaration. *See, e.g.*, ECF No. 119 at 15. Defendants incorrectly contend that the admissibility of the Tegzes Declaration bears on the admissibility of the Adams and Kanelakis declarations. ECF No. 115 at 1; ECF No. 119 at 4. Instead, the moving party, here FDA, unambiguously must demonstrate that the evidence satisfies one of the recognized exceptions, none of which involves consideration of whether another party also moved for consideration of extra-record evidence.

FDA also argues that its declarations explain "complex or technical" subject matter and provide "relevant factors" needed for the Court to understand the Tegzes Declaration. In reality, these "explanations" consist of a recitation of agency guidance documents and regulations and improper arguments seeking to demonstrate that FDA's approval of Experior complied with the Administrative Procedure Act. The Court is obligated to undertake a "sufficiently probing"

review of the agency action, *Locke*, 776 F.3d at 994, and the record in front of the Court is lengthy and scientific. However, that does not mean that it should consider extra-record evidence that does not fit the *Lands Council* exceptions. The Ninth Circuit demands that courts strike extra-record materials that do not meet the established exceptions, so the FDA declarations cannot properly be considered.

I. Defendants Have Failed to Demonstrate That Either the Adams or Kanelakis Declarations Satisfy the "Technical Terms or Complex Subject Matter" Exception.

The "technical or complex" exception requires that an extra-record declaration "aid the Court's understanding" of the record by providing context or explanations. *Pinnacle Armor, Inc. v. United States*, 923 F. Supp. 2d 1226, 1244 (E.D. Cal. 2013); *see Cascadia Wildlands Project v. U.S. Forest Serv.*, 386 F. Supp. 2d 1149, 1158 (D. Or. 2005) (stating that extra-record material may only be considered when it is "needed to explain 'technical or complex subject matter'" to the court). Here, FDA has failed to show that either the Adams or the Kanelakis declarations satisfy the "technical or complex" exception. Instead of aiding the court's understanding of the record, FDA states its declarations are meant to explain the Tegzes Declaration itself. ECF No. 119 at 4. However, the agency's declarations accept and confirm many of the technical explanations found in the Tegzes Declaration. For example, after explaining the record studies, Dr. Tegzes explains that Experior's effects can only be verified by measuring emissions from waste, not through any measurable effect in cows. ECF No. 79-1 at ¶ 218. The Adams Declaration does not disagree: "This information, while interesting from an academic perspective, is unnecessary." ECF No. 106-1 at ¶ 29. Adams then goes on to explain why legally, the Court need not concern itself with the fact that the effects of Experior cannot be evaluated in real-life settings. *Id.*; ECF No. 119 at 7–8; *see also* ECF No. 106-1 at ¶ 14 (accepting Dr. Tegzes' explanation of blood urea nitrogen at ECF No. 79-1 at ¶¶ 164–68); ECF No. 106-1 at ¶ 17 (agreeing with Dr. Tegzes' finding, at ECF No. 79-1 at ¶¶ 171–72, that some treated cows in a study had low kidney weights); ECF No. 106-1 at ¶ 22 (conceding that feed was only tested for mycotoxins at the beginning of a study, not throughout or after, as Dr. Tegzes explains, at ECF No. 79-1 at ¶¶ 186–87); ECF No. 106-1 at ¶ 33 ("Dr. Tegzes is correct in his analysis of the

relationship between dietary protein and ammonia emissions [citing ECF No. 79-1 at ¶¶ 146–50].”); ECF No. 106-2 at ¶¶ 14, 20 (agreeing with Dr. Tegzes’ explanation, at ECF No. 79-1 at ¶¶ 47–48, that the human studies tested the drug’s anti-obesity effects); ECF No. 106-2 at ¶ 23 (acknowledging that, as the Tegzes Declaration explains, ECF No. 79-1 at ¶¶ 83–85, the human studies did not include urodynamic testing); ECF No. 106-2 at ¶ 25 (agreeing with the Tegzes Declaration, ECF No. 79-1 at ¶¶ 83, 92, that the human studies did not test β_3-adrenergic receptor agonism).

FDA concedes that both the Adams and Kanelakis declarations dedicate significant time to quoting, summarizing, or otherwise reiterating material already in the administrative record rather than explaining it in simpler or clearer terms. ECF No. 119 at 6. This cuts directly against established precedent in the Ninth Circuit, where declarations that are redundant of the record are stricken. *E.g.*, *Sw. Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1451 (9th Cir. 1996) (rejecting admission of documents containing “information [that] already exists in the record”); *Border Power Plant Working Grp. v. Dep’t of Energy*, 467 F. Supp. 2d 1040, 1051–52 (S.D. Cal. 2006) (“The Court may not rely on extra-record evidence when it can review the very same evidence submitted for the record.”); *Ctr. for Sierra Nevada Conservation v. Berry*, No. CIV-S-02-325 LKK/JFM, 2005 WL 8176532, at *8 (E.D. Cal. Feb. 17, 2005) (striking a declaration that “simply points to sections of the Pacific Deer Herd Management Plan that supports defendants’ position”); *League of Wilderness Defs. v. Marquis-Brong*, 259 F. Supp. 2d 1115, 1127 (D. Or. 2003) (striking agency declaration comprised of “quotations from the [administrative record] and a report . . . that is contained in the [administrative record]”).

Ignoring this case law, FDA attempts to justify inclusion of these impermissible redundancies on the grounds that Drs. Adams and Kanelakis “determined that these were the most appropriate means” of explaining the Tegzes Declaration to the Court. ECF No. 119 at 6. However, it is not for declarants to determine what is admissible under the “technical or complex” exception. Furthermore, merely pointing to the record without providing any technical explanation suggests that such material is well within the grasp of the Court—and thus does not

require technical explanation by an expert.[1] FDA then goes on to justify its redundant declarations by claiming they "guide the Court's consideration." ECF No. 119 at 7. Such so-called "guiding" does not fall under the "technical or complex" exception if nothing technical or complex is explained and is thus not a recognized ground to admit extra-record evidence. *See Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005) (the four recognized exceptions are to be "narrowly construed"); *Pinnacle Armor*, 923 F. Supp. 2d at 1244 (striking a declaration that simply characterized the record without explaining complex material).

In addition to simply reiterating agency guidance and regulations, these recitations in FDA's declarations are legal conclusions masquerading as "technical" explanations. FDA maintains that its declarations cite and quote FDA guidance documents and regulations at length because the Tegzes Declaration does not. ECF No. 119 at 6–7. It is for this reason that the bulk of FDA's declarations are devoted to opining that Experior was approved according to the law, which, in FDA's eyes, makes the Tegzes Declaration "misleading." *See, e.g.*, ECF No. 106-2 at ¶ 46 (stating the record studies "followed the standard toxicological testing outlined in the Agency Guidance"); *id.* at ¶ 37 (same); ECF No. 106-1 at ¶ 7 (declaring that Elanco's studies were sufficient because they were "[c]onsistent with the standards in FDA regulations and recommendations in guidance documents"). Plaintiffs raised the issue of FDA's declarations asserting improper legal conclusions, and FDA retorts that any discussion of agency guidance and regulations in its declarations cannot possibly be a legal conclusion because guidance documents are non-binding and because Dr. Adams and Dr. Kanelakis were only describing their real-life experiences as reviewers of Experior. *See* ECF No. 119 at 12–13 (depicting the declarations' citations to agency documents and regulations as describing memories of the reviewers). However, when Drs. Adams and Kanelakis state that FDA's approval of Experior

[1] It follows then—in contrast to the Tegzes Declaration, which provides technical explanation—that the appropriate means to raise these matters would be within the briefing, not in a redundant extra-record declaration. *See Phoenix Light SF Ltd. v. Bank of New York Mellon*, No. 14-CV-10104 (VEC), 2019 WL 5957221, at *4, n.4 (S.D.N.Y. Nov. 13, 2019) (citing to other material already before the court "is properly done by attorneys in their legal briefs, not by the expert in a separate declaration").

allegedly followed agency guidance and regulations, they are surmising that the agency's decision-making was well-reasoned and entitled to deference. *See, e.g.*, *San Luis & Delta-Mendota Water Auth. v. U.S.*, 672 F.3d 676, 708 (9th Cir. 2012) (stating agency guidance memo may be entitled to "some deference" (quoting *Reno v. Koray*, 515 U.S. 50, 61 (1995))); *Hofstetter v. Chase Home Fin., LLC*, No. C 10–01313 WHA, 2010 WL 3259773, at *9 (N.D. Cal. Aug. 16, 2010) (explaining persuasive agency guidance documents constitute informed judgment and are entitled to respect). Such legal conclusions are improper in extra-record evidence and do not fit the *Lands Council* "technical or complex" exception.

II. The "Relevant Factors" Exception Does Not Apply to FDA's Post Hoc Rationalizations and Rebuttal Arguments.

Extra-record evidence is admissible if it "is necessary to determine whether the agency has considered all relevant factors and has explained its decision." *Lands Council*, 395 F.3d at 1030 (quotations and citations omitted). The purpose of the "relevant factors" exception is to allow a party *challenging* agency action to provide extra-record evidence showing an agency failed to consider an important aspect of its decision. *Id.* This exception is not meant for use by agencies to fortify unexplained reasoning in the record, and it is not meant for use by agencies as a tool to rebut a challenging party's argument. *See Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, No. 3:01–CV–00640–SI, 2015 WL 423090, at *1 n.2 (D. Or. Feb. 2, 2015) (stating that any extra-record rebuttal declarations would be permitted so long as "such declarations follow the requirement of being offered only for the narrow purposes permitted in *Lands Council*.").

Likewise, Courts may not use "extra-record evidence 'to determine the correctness or wisdom of the agency's decision.'" *Locke*, 776 F.3d at 993 (quoting *Asarco, Inc. v. U.S. Env't Prot. Agency*, 616 F.2d 1153, 1160 (9th Cir. 1980)). This is true whether applied to a plaintiff's or agency's extra-record evidence. Yet by attempting to shoehorn its rebuttal declarations into the "relevant factors" exception, FDA uses the Adams and Kanelakis declarations to proffer post hoc rationalizations and explain why its decisions were proper.

A. Agency Extra-Record Evidence That Provides New or Contradictory Justifications Are Impermissible.

Plaintiffs describe at length the efforts the Adams and Kanelakis declarations go to create

novel foundations for FDA's approval of Experior, ECF No. 109 at 10–15, and FDA does not deny that its declarations present post hoc rationalizations. *See* ECF No. 119 at 11 ("Federal Defendants are of necessity responding to Dr. Tegzes' post hoc critiques of FDA[]."). Instead, FDA argues that if the Court considers the Tegzes Declaration, it should consider the Adams and Kanelakis declarations because they provide responsive explanations of FDA's actions—explanations which are not in the record. ECF No. 119 at 11.

First, FDA is wrong to characterize Plaintiffs' declaration as a "post hoc critique," ECF No. 119 at 11, as it merely explains the administrative record and provides context as to why the factors raised by Plaintiffs in their briefing are relevant. Additionally, Plaintiffs—as well as the rest of the public—learned of Experior only after FDA approved the drug. This is not a case where Plaintiffs had an opportunity to participate in a notice and comment rulemaking process before the agency acted. An agency's superior ability to shape the record is why courts allow plaintiffs to supplement the record with materials the agency "did not include . . . whether by design or accident." *Univ. of Colorado Health v. Azar*, 486 F. Supp. 3d 185, 200 (D.D.C. 2020) (citations omitted). Contrary to FDA's framing, Plaintiffs and FDA are not on the same footing, and courts do not blindly apply the "relevant factors" exception to allow agencies to change their reasoning after-the-fact whenever they are challenged. *See, e.g.*, *Earth Island Inst. v. U.S. Forest Serv.*, 442 F.3d 1147, 1162 (9th Cir. 2006), *abrogated in part by Winter v. Nat. Res. Def. Council*, 555 U.S. 7 (2008) (admitting plaintiff declaration under relevant factor exception as agency had failed to consider the relevant factor of tree mortality); *Paradise Ridge Def. Coal. v. U.S. Army Corps of Eng'rs*, No. 1:22-cv-00122-BLW, 2022 WL 1910244, at *7 (D. Idaho June 3, 2022) (admitting plaintiff declaration under relevant factor exception because agency had failed to consider factors relevant to whether the project exceeded the acreage of its permit); *Stop B2H Coal. v. Bureau of Land Mgmt.*, 552 F. Supp. 3d 1101, 1121 (D. Or. 2021) (admitting plaintiff exhibits demonstrating that agency failed to consider the proper four-mile boundary).

Second, FDA's reliance on *Border Power Plant Working Group v. Department of Energy*, 467 F. Supp. 2d 1040, 1051 (S.D. Cal. 2006), for the premise that an agency's rebuttal declarations cannot be considered a "post hoc rationalization" is mistaken. ECF No. 119 at 6, 11.

In that case, *defendant-intervenor* Termoelectrica U.S. (T-US) submitted extra-record declarations, which the plaintiffs objected to as post hoc justifications meant to fill gaps in agency decision-making. 467 F. Supp. 2d at 1051. The court stated that "[t]he concept of the Simoes Declaration as a 'post hoc rationalization' is initially dubious because T-US is the party submitting the declaration. If the agencies were trying to prop up the FEIS's analysis with the Simoes Declaration, one would have expected the federal defendants to submit the declaration. . . ." *Id.* at 1051 n.12. By distinguishing between the defendant agencies and the defendant-intervenor company, the court showed that only an *agency's* extra-record declaration may be considered "post hoc rationalizations." FDA cites no other case to support its argument that after-the-fact agency justifications fall under the "relevant factors" exception.

Third and relatedly, FDA's citation to internet articles, webpages, and guidance documents not included in the administrative record is an improper attempt to shore up its unsupported reasoning. "Just as we will not allow the agency to supply post-hoc rationalizations for its actions, so 'post-decision information. . . may not be advanced as a new rationalization either for sustaining or attacking an agency's decision.'" *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 604 (9th Cir. 2014) (quoting *Sw. Ctr. for Biological Diversity*, 100 F.3d at 1450). For instance, the Tegzes Declaration cites to four separate documents in the record to explain that high levels of protein in cows' diets can have negative environmental effects, whereas lower protein levels in cows' diets may result in beneficial environmental effects, like reduced nitrogen and ammonia emissions. ECF No. 79-1 at ¶¶ 151–52. This was merely background explanation of materials in the record to help describe various testing done by Elanco. *Id.* at ¶ 153.[2] In response, FDA stated that it was "necessary" for the Adams Declaration to cite a webpage on protein nutrition for cows from 2019 because it was the only way to respond to the Tegzes Declaration. ECF No. 119 at 14. It is axiomatic that the Adams Declaration's reference to new materials that post-date Experior's approval in response to the

[2] FDA mistakenly states that the Tegzes Declaration called for the testing of low-protein diets on cows to reduce emissions, *see* ECF No. 119 at 14 (citing Tegzes Decl. at ¶ 153), when in reality, Dr. Tegzes was providing explanatory background for testing conducted by Elanco.

Tegzes Declaration's explanatory description of cow nutritional requirements from the record is an improper, post hoc rationalization. Such materials do not meet the "relevant factors" exception in the Ninth Circuit. *See Cachil Dehe Band of Wintun Indians of Colusa Indian Cmty. v. Zinke*, 889 F.3d 584, 601 (9th Cir. 2018).

B. An Extra-Record Declaration Cannot be Used to Solely to Rebut Plaintiffs.

The Ninth Circuit has four "narrow exceptions" to the general rule that judicial review of agency action is limited to the administrative record, including the "relevant factors" exception. Rebutting a plaintiff's declaration does not fall under any of these exceptions. *See Lands Council v. Powell*, 395 F.3d at 1029–30; *W. Watersheds Project v. Bureau of Land Mgmt.*, No. 3:11-CV-00053, 2012 WL 13937, at *5 (D. Nev. Jan. 4, 2012) (stating that proposed rebuttal declaration failed to independently satisfy any of the recognized exceptions); *see also High Sierra Hikers Ass'n v. Weingardt*, No. C-00-01239 EDL, 2007 WL 3231698, at *2 (N.D. Cal. Oct. 30, 2007) ("[T]he standard for admitting extra-record evidence is not simply relevance.").

FDA cannot hitch its wagon to the Tegzes Declaration and argue that its declarations meet the *Lands Council* exceptions by mere association. The Tegzes Declaration "operate[s] to identify and plug holes in the administrative record," *Lands Council*, 395 F.3d at 1030, while the FDA declarations attempt to rebut the Tegzes Declaration and argue that relevant factors were considered. For example, FDA states that Dr. Adams' declaration is necessary to clarify the ambient temperature ranges of one study, when this information either is, or should be, clearly stated in the record and therefore easily could have been simply cited in FDA's brief. ECF No. 119 at 7.

Rebuttal declarations are not admissible solely under the "relevant factors" exception when they do not independently meet the exception, and FDA provides no authority to the contrary. The *only* case FDA cites to support its proposition is *Earth Island Institute v. U.S. Forest Service*, where the Ninth Circuit relied on extra-record declarations from both an agency and a challenging party. 442 F.3d 1147, 1163–69 (9th Cir. 2006), *abrogated in part by Winter v. Nat. Res. Def. Council*, 555 U.S. 7 (2008). In addition to the case being at the preliminary

injunction stage—where evidentiary standards are relaxed[3]—the court never applied the *Lands Council* exceptions to the agency's expert declarations. *Id.* Nor did the court create a rebuttal declaration exception, where agency declarations are admissible if a plaintiff's declaration is admissible under *Lands Council*. *See* ECF No. 119 at 7 (incorrectly asserting that *Earth Island Institute* created a rebuttal declaration exception).

C. An Extra-Record Declaration Cannot Be Used to Demonstrate the Agency Complied with the APA.

The proper manner for FDA to argue and demonstrate to the Court that the agency considered all "relevant factors" is in its briefing, with reference to the administrative record.[4] *See, e.g.*, *Phoenix Light*, 2019 WL 5957221, at *4 n.4 (striking parts of a declaration for countering opposing party's arguments), *see also Camp v. Pitts*, 411 U.S. 138, 142 (1973) (arbitrary and capricious review of agency action should focus on "the administrative record already in existence, not some new record made initially in the reviewing court"); *San Francisco BayKeeper v. Whitman*, 297 F.3d 877, 886 (9th Cir. 2002) (review of final agency action "is based on a set administrative record").

Unable to support its assertion that it considered all relevant factors by pointing to the Administrative Record, FDA is forced to improperly rely on Dr. Adams' and Dr. Kanelakis' declarations. ECF No. 119 at 1 ("[M]any of Dr. Adams' and Dr. Kanelakis' explanations are *necessary* to show that, contrary to the Tegzes Declaration, the decision-making of the U.S. Food and Drug Administration ("FDA") accounted for all relevant factors.") (emphasis added). Yet if those explanations do not exist in the record, they are improper. A declaration that proffers extra-

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[3] *See Herb Reed Enters., LLC v. Fla. Ent. Mgmt., Inc.*, 736 F.3d 1239, 1250 n.5 (9th Cir. 2013) ("Due to the urgency of obtaining a preliminary injunction at a point when there has been limited factual development, the rules of evidence do not apply strictly to preliminary injunction proceedings." (citation omitted)).

[4] If FDA cannot point to material from the Administrative Record that addresses the relevant factors identified by Plaintiffs, then the agency failed to sufficiently consider these factors. *See, e.g.*, *Or. Nat. Desert Ass'n v. Bureau of Land Mgmt.*, 625 F.3d 1092, 1120 (9th Cir. 2010) (stating that when an agency does not provide a rationale found in its decision and record documents, "the [agency's] argument is simply a *post hoc* rationalization advanced. . . to defend against past agency action against attack." (citation and quotations omitted)).

record evidence but fails to independently meet the *Lands Council* exceptions cannot be admitted no matter how "necessary" the agency believes it to be to justify its decision.

Defendants have not met their burden of showing the Adams or Kanelakis declarations each independently meet the "relevant factors" exception. Instead, FDA's rebuttal declarations provide post hoc rationalizations to justify the agency's failure to consider relevant factors, so the Court should strike the declarations.

III. The Court Should Grant Plaintiffs' Motion to Strike.

When a proffered declaration does not fit one of the four exceptions recognized by the Ninth Circuit, the proper remedy is to strike that declaration from the record. *See Nw. Env't Advocs. v. Nat'l Marine Fisheries Serv.*, 460 F.3d 1125, 1145 (9th Cir. 2006) (holding that lower court decision to strike entire declaration, "[g]iven the failure of [the agency] to establish any exception to the general rule against allowing extra-record evidence," was not an abuse of discretion). Here, Defendants have failed to demonstrate that the Adams or the Kanelakis declarations satisfy either the "technical or complex" or the "relevant factor" *Lands Council* exceptions. As such, the Court should grant the motion to strike with respect to both declarations.

FDA cites an earlier statement by the Court as supposedly allowing Defendants to proffer these responsive declarations. ECF No. 119 at 15. In the Order cited by FDA, the Court suggests that if Plaintiffs' declaration is proffered for the purpose of explaining technical issues, which is perfectly permissible, then Defendants may similarly submit a declaration explaining why Plaintiffs' declaration's technical explanations are wrong. ECF No. 89 at 2. This statement by the Court is uncontroversial; all it says is that Defendants may also proffer a declaration. The four recognized exceptions still apply equally to declarations submitted by both parties. The Court approved the submission of declarations, but it did not approve the declarations that were ultimately submitted. As FDA has failed to demonstrate that either of their proffered declarations satisfy either of the relevant exceptions, the Court's prior invitation to submit declarations does not create safe harbor from the well-established precedent requiring the Court to strike these declarations.

CONCLUSION

For the foregoing reasons, neither the Adams Declaration nor the Kanelakis Declaration meet any of the *Lands Council* exceptions for the admission of extra-record evidence. Plaintiffs respectfully request the Court grant Plaintiffs' Motion to Strike FDA's Extra-Record Declarations.

Dated: January 23, 2023

Respectfully submitted,

/s/ *Cristina Kladis*
Cristina Kladis (SBN 332812)
Larissa U. Liebmann (*pro hac vice*)
Animal Legal Defense Fund
525 E. Cotati Avenue
Cotati, CA 94931
T: (707) 795-2533
ckladis@aldf.org
lliebmann@aldf.org

Paige M. Tomaselli (SBN 237737)
Grime Law, LLP
5630 Venice Blvd. Suite 544
Los Angeles, CA 90019
T: (619) 339-3180
ptomaselli@grimelaw.com

Attorneys for Plaintiffs